DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 19, 2015

iRhythm Technologies, Inc.
Rich Laguna
Director QA/RA
650 Townsend Street, Ste 380
San Francisco, California 94103

Re: K143513
Trade/Device Name: ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, DXH
Dated: May 15, 2015
Received: May 18, 2015

Dear Rich Laguna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_K143513_____

Device Name: ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service

Indications for Use:

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

Prescription Use __**X**__ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5
510(k) SUMMARY

This summary of the 510(k) premarket notification for the ZEUS System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

SECTION 5
510(k) SUMMARY

510(k) Notification K 143513

GENERAL INFORMATION

Applicant:

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650 Townsend Street, Suite 380
San Francisco, CA 94103
U.S.A
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:

Rich Laguna
Director Quality & Regulatory Affairs
eMail: rlaguna@irhythmtech.com
Phone: 415-632-5749
Fax: 415-632-5701

Date Prepared: December 10, 2014

DEVICE INFORMATION

Classification:

Recorder, Magnetic Tape, Medical, 21 CFR§870.2800
Computer, diagnostic, programmable, 21CFR§870.1425
Transmitters and receivers, electrocardiograph, telephone, 21CFR§870.2920

Product Codes:

DSH, DQK, DXH

Trade Name:

ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service

Generic/Common Name:

Medical magnetic tape recorder

PREDICATE DEVICE(S)

ZEUS (ZIO ECG Utilization Services) System [K142681]
ZIO PATCH [K121319]
EPI MINI [K121628]

SECTION 5
510(k) SUMMARY

INDICATIONS FOR USE

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

PRODUCT DESCRIPTION

The ZIO® SR ECG Monitoring Service consists of three components: (1) ZIO SR Patch Recorder with Bluetooth technology, (2) ZIO SR Wireless Gateway, and (3) ZIO ECG Utilization Service System.

The ZIO® SR Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to symptomatic data transmission for up to 14 days. The ZIO® SR Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button which marks the continuous record and initiates a wireless transfer of an ECG strip of 90-second duration. The wireless transfer of data is enabled by the ZIO® SR Gateway, which requires proximity and reception but no patient interaction. The patient is encouraged to fill out a log to document symptomatic events, which will support symptom-rhythm correlation in the ZIO SR Report. Alternatively, the patient can enter symptom logs and view received transmissions via an online patient portal.

At the conclusion of the wear period (up to 14 days), the patient removes the ZIO® SR Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of symptomatic or continuous ECG data at iRhythm's Clinical Center (iCC) the ECG data is downloaded, the data is processed through the algorithm and delivered to the QA Tool module where the results are reviewed and/or adjusted by iRhythm Certified Cardiographic Technicians (CCT's) for accuracy. iRhythm employed and trained Patch in-take and CCT personnel follow internal procedures for processing and are made aware of algorithm performance anomalies. Any software anomalies are visible to and manually corrected by iRhythm Technologies CCT's during the QA review and/or Patch Report edits. The CCT generates a final report of the ECG findings contained within the data; thereby enabling the provision of a complete ECG processing and analysis service.

Upon explicit request from a clinician responsible for the patient's healthcare, longer segments of ECG data from the continuous recording on the Patch can also be wirelessly retrieved during the wear period.

Automated ECG analysis performance was quantified for any claimed analysis metrics. The resulting statistics demonstrate sensitivity and positive predictivity levels which satisfy requirements and minimize safety or efficacy concerns.

SECTION 5
510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE

The indications for use for the ZIO® SR ECG Monitoring Service are substantially equivalent to the indications for use for the predicate devices. The performance testing results demonstrate that any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Therefore, the ZIO® SR ECG Monitoring Service is substantially equivalent to the predicate device.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

There are no required FDA performance standards for the ZIO® SR ECG Monitoring Service. All necessary performance testing was conducted on the ZIO® SR ECG Monitoring Service to support determination of substantial equivalence to the predicate devices. The results confirm by examination and provision of objective evidence that the design output met the design input requirements in conformance with the following list of recognized consensus standards:

- ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices
- IEC 60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests
- IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-47:2012, Medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)
- EC12:2000/(R)2010, disposable ecg electrodes. (Cardiovascular)
- ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

CONCLUSION

The ZIO® SR ECG Monitoring Service is substantially equivalent to the predicate devices.